

# Psychological Intervention Alcohol Misuse Learning Disability

|                                        |                                                               |                                                                                                              |
|----------------------------------------|---------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>17/12/2013   | <b>Recruitment status</b><br>No longer recruiting             | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>17/12/2013 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results            |
| <b>Last Edited</b><br>12/09/2017       | <b>Condition category</b><br>Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data                                                         |

## Plain English summary of protocol

### Background and study aims

Problems associated with alcohol misuse are becoming increasingly common in people with learning disabilities due to much more ready access to alcohol associated with living in the community. There are no specific treatments for people with mild to moderate learning disabilities that can help with harmful use of alcohol. The aim of this study is to examine whether a psychological intervention that is available to adults with Alcohol Use Disorders (AUD), called Extended Brief Intervention (EBI), can be delivered to people with mild to moderate learning disabilities. The National Institute of Health and Clinical Excellence recommends EBI for people with AUD before they receive any more specialist treatment. It includes three to five sessions with a trained professional and follow up in addition to usual care (medical, nursing and social input). There is one study of EBI in people with learning disabilities. These people were patients in a psychiatric hospital and was not compared with usual care. Therefore, the aim of this study is to explore if and how EBI could be offered in the community.

### Who can participate?

People from community learning disabilities services in Hertfordshire and North Essex, aged over 18, who have mild or moderate learning disability and who use alcohol in a harmful way.

### What does the study involve?

Participants are randomly allocated to one of two groups. Group 1 receive their usual care with an additional half-hour EBI session every week and a final one-hour EBI session at eight weeks. Group 2 receive their usual care. The researchers investigate if the study is acceptable, if service users would like to take part, if they can engage clinicians, and if the research questionnaires perform well. Participants and their carers are assessed at the start of treatment, the end of treatment and at 3 months. At around week 12 service users, carers and clinicians are interviewed to find out what they thought of EBI.

### What are the possible benefits and risks of participating?

Participants have the chance to receive a treatment for their alcohol problem. This treatment is modified to meet the needs of people with mild to moderate learning disabilities. No side

effects are expected from this treatment. If the study shows that it is feasible to offer EBI to people with mild to moderate learning disabilities, then a bigger study will be carried out to investigate if the addition of EBI to usual care is a better treatment than usual care alone.

Where is the study run from?

The study is organised by the Hertfordshire Partnership NHS Foundation Trust in collaboration with University College London. It takes place in Hertfordshire and North Essex and recruits from all 10 community learning disabilities teams.

When is the study starting and how long is it expected to run for?

January 2014 to February 2015

Who is funding the study?

National Institute of Health Research (UK)

Who is the main contact?

Dr Christos Kouimtsidis

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## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

**Protocol serial number**

15271

## Study information

**Scientific Title**

A feasibility study of a psychological intervention to address alcohol misuse for people with mild to moderate learning disabilities living in the community

**Study objectives**

Can we design a feasible large scale randomised controlled trial that will address whether Extended Brief Intervention is more effective than usual care in helping persons with mild to moderate learning disabilities to manage hazardous or harmful drinking?

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

NRES Committee South Central - Berkshire, 03/05/2013, ref: 13/SC/0143

### **Primary study design**

Interventional

### **Study design**

Randomised interventional treatment trial

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Topic: Mental Health Research Network; Subtopic: Addictions, Learning difficulties development disorders; Disease: Addictive Substances alcohol, Learning difficulties

### **Interventions**

Based on the guidelines by the MRC, our feasibility study is in three stages:

1. Adaptation of the intervention from existing literature, feedback from professionals and service users with learning disabilities and the therapist (4 months)
2. Completion of a single-blind randomised controlled trial of EBI and usual care versus usual care to investigate whether the study is acceptable and service users can be recruited, whether we can engage clinicians, and whether the instruments we have chosen perform well (24 months)
3. A qualitative study to examine what service users, carers and service providers thought of EBI (overlaps with phase 2)

The duration is 30 months in total. We will use the data from the study to apply for a large trial.

As this is a feasibility study we have not performed a sample size calculation. However, we aim to recruit up to 50 (minimum 40) participants, which will allow us to analyse the data in terms of descriptive statistics and point and interval estimations.

EBI and usual care versus usual care

Extended Brief Intervention, Extended Brief Intervention (EBI) modified as described in stage 1. It will be provided over five half hour weekly sessions and there will be a final one hour session after eight weeks.; Follow Up Length: 3 month(s); Study Entry : Single Randomisation only

### **Intervention Type**

Drug

### **Phase**

Not Applicable

**Primary outcome(s)**

Reduction in primary outcome scores: the percentage of days of abstinence (PDAS) and percentage of days of heavy drinking

**Key secondary outcome(s)**

Secondary outcomes will be willingness to change, health status, service use and mental status  
Feasibility outcomes: weekly recruitment rates, loss to follow up, compliance rates (number of sessions attended) and basic costs

Completion rates are also measured to assess acceptability

**Completion date**

28/02/2015

**Eligibility****Key inclusion criteria**

Adults with mild to moderate learning disabilities aged 18 years who are known to professionals within the learning disabilities services as possibly having an alcohol problem will be eligible to be referred to the study. Once found to be eligible to take part, they will be further assessed with the WASI to assess their level of cognitive functioning (unless results from a previous cognitive assessment are available). Once consented to participate, they will be screened using the Alcohol Use Disorder Identification Test (AUDIT).

**Inclusion criteria:**

1. AUDIT score >8 and up to 19. We appreciate that the NICE (18) advice is to reduce scores in particular populations in which prevalence of AUD is lower than the general population such as older people, females and younger people. Local data, however, suggests that the prevalence of AUD in the local population with mild to moderate learning disability in contact with treatment services using AUDIT 8 as the cut-off point is 22.5%, which is similar to the prevalence in the general population. Therefore, we have decided to adopt the same cut-off AUDIT score as in the general population and to consider any changes, e.g. lowering the cut-off, following the findings from the study.
2. Residents in the area within the last 12 months.
3. Full Scale IQ<70 (+/5% CI).
4. Target Gender: Male & Female; Upper Age Limit 65 years; Lower Age Limit 18 years

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

All

**Key exclusion criteria**

1. Severe to profound learning disabilities
2. Non-English speaking
3. Receipt of treatment for alcohol-related problems in the last 12 months
4. Severe and enduring mental illness
5. Polysubstance misuse including alcohol where the illicit substance, e.g. cocaine/heroin /cannabis is the main problem

**Date of first enrolment**

06/01/2014

**Date of final enrolment**

28/02/2015

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Warren Court, Eric Shepherd Forensic Services**

Abbots Langley

United Kingdom

WD5 0HT

**Sponsor information****Organisation**

Hertfordshire Partnership Foundation NHS Trust (UK)

**ROR**

<https://ror.org/0128dmh12>

**Funder(s)****Funder type**

Government

**Funder Name**

NIHR (UK) - Research for Patient Benefit (RfPB); Grant Codes: PB-PG1111-26022

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

| Output type                          | Details      | Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------------------------------|--------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>      | results      | 12/05/2017   |            | Yes            | No              |
| <a href="#">Protocol article</a>     | protocol     | 25/03/2015   |            | Yes            | No              |
| <a href="#">HRA research summary</a> |              |              | 28/06/2023 | No             | No              |
| <a href="#">Other publications</a>   | study manual | 01/12/2017   |            | Yes            | No              |